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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-24

May 24, 2000

L.Hoyt Miller, M.D.
Castleton Family Physicians
8060 Knue Road, Suite 120
Indianapolis, IN 46250

Dear Dr. Miller:

We are writing you because on May 10, 2000, your facility was inspected by a representative of the State of Indiana, acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Level 1 finding at your facility:

1. Mammograms were processed on five (5) different days when the film processor was outside of the control limits.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of law which may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or

revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should also address the Level 2 findings that were listed on the inspection report that was provided to your facility at the close of the inspection. The Level 2 findings are:

1. The darkroom fog level density was measured to be 0.11 optical density units (O.D.) This level should be no greater than 0.05 O.D. units.

2. There was no formal written procedure for handling consumer complaints.

3. There was no formal written procedure for infection control including disinfection of the mammography equipment.

4. Corrective actions for film processor QC failures was not document in at least one instance.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the Level 1 and Level 2 violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate;
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food and Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Indiana radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html..

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

John P. Dempster

John P. Dempster
Acting District Director
Detroit District

Enclosures:a/s